IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

DEFENDANT APOTEX, INC.'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

THE PARTIES

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

ANSWER: Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

ANSWER: Admitted.

BACKGROUND

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the "'941 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '941 patent is currently set to expire on December 2, 2012. The '941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '941 patent is attached to this Complaint as Exhibit 1.

ANSWER: Apotex admits that United States Patent No. 5,358,941, entitled "Dry Mix Formulation For Bisphosphonic Acids With Lactose" was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the "'590 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '590 patent is currently set to expire on December 2, 2012. The '590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '590 patent is attached to this Complaint as Exhibit 2.

ANSWER: Apotex admits that United States Patent No. 5,681,590, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark Office on October 28, 1997 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '590 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

7. On December 15, 1998, United States Letters Patent No. 5,849,726 (the "'726 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '726 patent is currently set to expire on June 6, 2015. The '726 patent discloses and claims novel pharmaceutical compositions of anhydrous 4-amino-1-hydroxy-butylidene-1, 1-bisphosponic acid monosodium salt, as well as novel methods for treating and preventing bone loss with these compositions. A copy of the '726 patent is attached to this Complaint as Exhibit 3.

ANSWER: Apotex admits that United States Patent No. 5,849,726, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and Trademark Office on Decmeber 15, 1998 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '726 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

8. On December 28, 1999, United States Letters Patent No. 6,008,207 (the "'207 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '207 patent is currently set to expire on June 6, 2015. The '207 patent discloses and claims novel methods for administering anhydrous alendronate monosodium salt formulations. A copy of the '207 patent is attached to this Complaint as Exhibit 4.

ANSWER: Apotex admits that United States Patent No. 6,008,207, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and

Trademark Office on December 28, 1999 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '207 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

9 On July 18, 2000, United States Letters Patent No. 6,090,410 (the "'410 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '410 patent is currently set to expire on December 2, 2012. The '410 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '410 patent is attached to this Complaint as Exhibit 5.

ANSWER: Apotex admits that United States Patent No. 6,090,410, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and Trademark Office on July 18, 2000 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '410 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

10. On February 27, 2001, United States Letters Patent No. 6,194,004 (the "'004 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '004 patent is currently set to expire on December 2, 2012. The '004 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '004 patent is attached to this Complaint as Exhibit 6.

ANSWER: Apotex admits that United States Patent No. 6,194,004, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark

Office on February 27, 2001 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '004 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

11. On November 30, 1999, United States Letters Patent No. 5,994,329 (the "'329 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates entitled METHOD FOR INHIBITING BONE RESORPTION. The '329 patent is currently set to expire on July 17, 2018. The '329 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '329 patent is attached to this Complaint as Exhibit 7.

ANSWER: Apotex admits that United States Patent No. 5,994,329, entitled "Method For Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on November 30, 1999 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '329 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

12. On January 18, 2000, United States Letters Patent No. 6,015,801 (the "'801 patent") duly and legally issued to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II entitled METHOD OF INHIBITING BONE RESORPTION. The '801 patent is currently set to expire on July 17, 2018. The '801 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '801 patent is attached to this Complaint as Exhibit 8.

ANSWER: Apotex admits that United States Patent No. 6,015,801, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on January 18, 2000 to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II, and that a copy of the '801 patent is attached to the complaint. Apotex is without knowledge or information

sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

13. On May 1, 2001, United States Letters Patent No. 6,225,294 (the "'294 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II and John Yates entitled METHOD OF INHIBITING BONE RESORPTION. The '294 patent is currently set to expire July 17, 2018. The '294 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '294 patent is attached to this Complaint as Exhibit 9.

ANSWER: Apotex admits that United States Patent No. 6,225,294, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on May 1, 2001 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '294 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

14. Merck is the owner through assignment of the '941, '590, '726, '207, '410, '004, '329, '801 and '294 patents. Merck also owns an approved New Drug Application (NDA No. 20-560) for alendronate sodium tablets that are sold under its trademark FOSAMAX®.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. Merck listed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents in the Orange Book for its FOSAMAX® tablets.

ANSWER: Apotex admits that the '941, '590, '726, '207, '410, '004, '329, '801 and '294 patents are listed in the "Orange Book" for Fosamx® tablets and denies truth of the remaining averments in this paragraph.

16. The FDA granted a six-month period of market exclusivity beyond the patent terms for Merck's FOSAMAX® drug product due to the timely submission and acceptance of

pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX® tablets until six months after the expiration date of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX® tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

ANSWER: Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

ANSWER: Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX® pharmaceutical products have created due to their benefits and advantages.

ANSWER: Denied, accept to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax®.

COUNT I

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

21. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '941 patent, it was aware of the existence of the '941 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '941 patent at the time it filed ANDA No. 077-982; otherwise denied.

22. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '941 patent.

ANSWER: Denied.

23. On information and belief, the infringement by Apotex of the '941 patent was and is willful.

ANSWER: Denied.

24. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT II

25. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

26. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '590 patent, before the expiration of the '590 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

27. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '590 patent, it was

aware of the existence of the '590 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '590 patent at the time it filed ANDA No. 077-982; otherwise denied.

28. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '590 patent.

ANSWER: Denied.

29. On information and belief, the infringement by Apotex of the '590 patent was and is willful.

ANSWER: Denied.

30. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT III

31. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

32. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '726 patent, before the expiration of the '726 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

33. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '726 patent, it was aware of the existence of the '726 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '726 patent at the time it filed ANDA No. 077-982; otherwise denied.

34. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '726 patent.

ANSWER: Denied.

35. On information and belief, the infringement by Apotex of the '726 patent was and is willful.

ANSWER: Denied.

36. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT IV

37. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

38. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '207 patent, before the expiration of the '207 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

39. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '207 patent, it was aware of the existence of the '207 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '207 patent at the time it filed ANDA No. 077-982; otherwise denied.

40. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '207 patent.

ANSWER: Denied.

41. On information and belief, the infringement by Apotex of the '207 patent was and is willful.

ANSWER: Denied.

42. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT V

43. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

44. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '410 patent, before the expiration of the '410 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

45. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '410 patent, it was aware of the existence of the '410 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '410 patent at the time it filed ANDA No. 077-982; otherwise denied.

46. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '410 patent.

ANSWER: Denied.

47. On information and belief, the infringement by Apotex of the '410 patent was and is willful.

ANSWER: Denied.

48. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT VI

49. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

50. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '004 patent, before the expiration of the '004 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

51. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '004 patent, it was aware of the existence of the '004 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '004 patent at the time it filed ANDA No. 077-982; otherwise denied.

52. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '004 patent.

ANSWER: Denied.

53. On information and belief, the infringement by Apotex of the '004 patent was and is willful.

ANSWER: Denied.

54. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT VII

55. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

56. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '329 patent, before the expiration of the '329 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

57. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '329 patent, it was aware of the existence of the '329 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '329 patent at the time it filed ANDA No. 077-982; otherwise denied.

58. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '329 patent.

ANSWER: Denied.

59. On information and belief, the infringement by Apotex of the '329 patent was and is willful.

ANSWER: Denied.

60. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT VIII

61. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

62. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or sale of a drug product the use of which is claimed in the '801 patent, before the expiration of the '801 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

63. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '801 patent, it was aware of the existence of the '801 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '801 patent at the time it filed ANDA No. 077-982; otherwise denied.

64. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '801 patent.

ANSWER: Denied.

65. On information and belief, the infringement by Apotex of the '801 patent was and is willful.

ANSWER: Denied.

66. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT IX

67. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

68. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '294 patent, before the expiration of the '294 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

69. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '294 patent, it was aware of the existence of the '294 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '294 patent at the time it filed ANDA No. 077-982; otherwise denied.

70. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '294 patent.

ANSWER: Denied.

71. On information and belief, the infringement by Apotex of the '294 patent was and is willful.

ANSWER: Denied.

72. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

WHEREFORE, Defendant prays that Plaintiff take nothing from this action and its complaint be dismissed with prejudice, with costs assessed against Plaintiff.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The complaint and each Count thereof fails to state a claim upon which relief can be granted.

Second Affirmative Defense

After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNTERCLAIM

Counterclaimaint Apotex, Inc. for its counterclaim alleges as follows:

PARTIES AND JURISDICTION

1. Counterclaimant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

2. On information and belief, counterdefendant Merck, Inc. ("Merck") is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. This Court has subject matter jurisdiction under the patent laws, Title 35 of the U.S. Code; The Declaratory Judgment Act, 28 U.S.C. § 2201; and 28 U.S.C. § 1338.

4. Venue and personal jurisdiction are proper in this district because the counterdefendant, *inter alia*, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

COUNT I – DECLARATORY RELIEF

5. The '329 and '801 patents are invalid for at least the reasons set forth in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005).

6. Apotex cannot be held liable for infringement of the '941 patent at least because the claims of this patent are limited to a composition comprising excipients consisting essentially of anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate; whereas, Apotex's tablets will not comprise lactose (either anhydrous or hydrous) or croscarmellose sodium, but will comprise as excipients only manitol, microcrystalline cellulose and magnesium stearate.

7. Apotex cannot be held liable for infringement of the '590, '410, and '004 patents at least because the claims of those patents are limited to a tablet comprising a diluent selected

from anhydrous lactose and hydrous fast flow lactose; whereas, Apotex's tablets will not comprise anhydrous lactose or hydrous fast flow lactose.

8. Apotex cannot be held liable for infringement of the '726, '207, and '294 patents at least because the claims of those patents are limited to anhydrous Alendronate sodium; whereas, Apotex's tablets will not contain anhydrous Alendronate sodium.

9. As a consequence of the foregoing, there exists a justiciable controversy as to whether the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are valid and infringed. Apotex is entitled to a declaration that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or not infringed.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex prays for judgment:

A. Finding the '329 and '801 patents are invalid;

B. Finding the '941, '590, '726, '207, '410, '004, and '294 patents are not infringed;

C. Finding that this is an exceptional case under 35 U.S.C. § 285;

D. Awarding to Apotex its costs, expenses, and reasonable attorney's fees;

E. Awarding such other relief as the Court deems just and appropriate.

JURY DEMAND

Apotex demands trial by jury for all issues triable by jury.

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Dated: May 9, 2006

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on May 9, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

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